United States
Environmental Protection Agency

Office of Chemical Safety and
Pollution Prevention

General Population Ingestion Risk Calculations Update for P-17-0382

This is an update of general population Margin of Exposure (MOE=POD/Exposure Dose) risk calculations contained in the 07/30/2018 Standard Review of P-17-0382 (attached) which identified systemic risks for the general population exposed to the PMN via drinking water and fish ingestion. After the Standard Review was completed an updated Exposure Report dated 03/09/2018 was generated based on the Engineering Report dated 02/26/2018.

Per the 07/30/2018 Standard Review (posted in NCR) the POD used to assess human health risk is the **NOAEL of 300 mg/kg-bw/day** (based on altered liver and spleen weights seen at 1000 mg/kg-bw/day) from the Repeated Dose 28 Day toxicity in Rats Oral (Gavage) OECD 407 which tested the PMN. Per the SAT Report (posted in NCR) the PMN substance is expected to be moderately absorbed *via* all exposure routes based on physical/chemical properties. Therefore, risks of concern for dermal exposures were estimated assuming a high-end absorption factor of **60%** based on analysis of quantitative absorption data for chemicals identified as likely to be moderately absorbed.

The general population can be exposed to the PMN substance by ingestion of drinking water or fish taken from surface waters to which the PMN has been discharged after treatment at a wastewater treatment facility at a removal rate of 90%. The general population is predicted to be exposed to the PMN during USE as Engine Lubricant at [redacted] Unknown sites over [redacted] days/year. Releases to water are the result of drum residuals from cleaning liquid residuals from drums used to transport the raw materials.

As shown in the table below, all MOEs are acceptable (greater than the benchmark of 100) indicating that **systemic risk is not predicted** for adults or any subpopulations exposed to the PMN via ingestion of drinking water. In addition ingestion of fish taken from surface waters to which the PMN has been released will not result in risk to adults and if adults are not at risk the more sensitive subpopulations will not be at risk.

Supporting Documents (also posted in NCR)
P-17-0382_SR_Final_Typo Revised posted 07-30-2018.pdf
P-17-0382 EXP Rpt 03-09-2018.doc

Attachment
P-17-0382 GenPop MOEs via ingestion.xls

P-17-0382 GenPop Ingestion MOE 2018-10-05

General Population MOE Risk Calculations for Ingestion Exposures from the USE as Engine Lubricant at Unknown Sites. Risks via Ingestion are based on the Systemic NOAEL of 300 mg/kg-bw/day based on altered liver and spleen weights seen at 1000 mg/kg-bw/day from the Repeated Dose 28 Day toxicity in Rats Oral (Gavage) OECD 407 which tested the PMN. MOE = (NOAEL x Abs Rate) / ((PDR x Abs Rate) / BW). Benchmark (Acceptable) MOE is 100 for NOAEL-based assessment.

Exposure Scenarios and Values[1]	NOAEL (mg/kg-bw/day)		NOAEL Route Absorption Rate[2]		Acute Dose Rate (mg/kg/day)		Exposure Route Absorption Rate[2]		Calculated MOE (Benchmark MOE=100)
USE as Engine Lubricant at 253 Unknown sites over 833 days/year									
DW Adults ≥21 yrs	300	x	60%	÷	0.00000427	x	60%	=	70257611
DW Infants ≤1 yr (Scaling Factor=4.17)	300	x	60%	÷	0.00001781	x	60%	=	16848348
DW Babies 1-2 yrs (Scaling Factor=1.63)	300	x	60%	÷	0.00000696	x	60%	=	43102829
DW Pregnant Women (Scaling Factor=1.02)	300	x	60%	÷	0.00000436	x	60%	=	68880011
DW Lactating Women (Scaling Factor=1.31)	300	x	60%	÷	0.00000559	x	60%	=	53631764
Fish Ingestion, Adults ≥21 yrs	300	x	60%	÷	0.00001720	x	60%	=	17441860

[1] General Population Adult Drinking Water (DW) and Fish Ingestion (FI) ADRs are from the 03/09/2018 Exposure Report. The values are generated using E-FAST which assumes a 100% absorption rate, and uses an adult male body weight of 80 kg. Subpopulation DW doses are derived using Drinking Water Scaling Factors provided by the Exposure Assessment Tech. Team and are based on Exposure Factors Handbook (2011) drinking water ingestion rates (EFH Table 3-1). No Scaling Factors have been derived to calculate Fish Ingestion ADRs for subpopulations, however if Adults are not at risk via Fish Ingestion then subpopulations will not be at risk.

[2] Moderately absorbed all routes (p/chem properties). Per RAD Qualitative Absorption Approaches for Assessment of PMN Chemicals (2016), qualitative values for absorption used are Nil <0.1%; Poor =0.1-15%; Moderate >15-60%; Good=61-100%. To be conservative the high end of the range is used.